

**BLA Number 125752**  
**Sequence No. 0020**

November 05, 2021

Marion Gruber, PhD  
Director, Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration  
Document Control Center  
10903 New Hampshire Avenue  
WO71, G112  
Silver Spring, MD 20993-0002

**Submission Type: TC Meeting Minutes and Follow-up**

Dear Dr. Gruber:

Reference is made to BLA 125752 for the initial Biologics License Application (BLA) for mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2) currently under review with the agency.

The purpose of this submission is to submit meeting minutes and follow-up information from the teleconference between Moderna and CBER on 28 October 2021 regarding datasets. The following documents are included in the submission:

- define
- 28Oct21 – To FDA – mRNA-1273 – BLA 125852 TC [meeting minutes and follow-up information]
- I-ae-solicited-term-by-subj-exarm-2021-05-04 [lookup table] pertinent to items 4a, 4b, and 6
- CE Mapping example document pertinent to item 10
- Therapeutic Area User Guide for Vaccines V1.1 and TAUG-VAX documents pertinent to item 10

If FDA has any questions, please do not hesitate to contact me directly at (617) 417-4428 or at [michelle.olsen@modernatx.com](mailto:michelle.olsen@modernatx.com).

This eCTD submission has been prepared by PPD Development, Inc. in full compliance with ICH and FDA guidance. The eCTD has been verified and confirmed to be virus and spyware free. PPD utilizes Palo Alto Traps v4.2.2. All technical questions should be directed to (b) (6) at PPD (b) (6) or email at (b) (6).

Yours Sincerely,

Michelle  
Olsen

Digitally signed by Michelle  
Olsen  
Date: 2021.11.05 13:58:22  
-04'00'

Michelle Olsen  
Associate Director, Regulatory Affairs Strategy  
ModernaTX, Inc.  
200 Technology Square  
Cambridge, MA 02139  
Tel.: (617) 417-4428; Fax: (b) (6)  
Email: michelle.olsen@modernatx.com